K023678

AMENDMENT 7

510(k) Summary

JAN 2 3 2003

January 10, 2003

Applicant: Aesthetic and Reconstructive Technologies, Inc. (AART)
3545 Airway Drive, Suite 108
Reno, NV 89511
(775) 853-6800 / FAX (775) 853-6805

Contact Person: Catherine Riple
Consultant for AART, Inc.
(805) 239-1059

Proprietary Name: DIMISIL Scar Gel
Common Name: Medical Grade Silicone Elastomer
Classification Name: Elastomer, Silicone, for Scar Management

Substantial Equivalence: The DIMISIL Scar Gel is substantially equivalent in function, design, performance and materials to the Kelocote marketed by Allied Biomedical Corporation of Ventura, CA and the Kelocote Scar Gel marketed by Hanson Medical, Inc.of Kingston, WA.

Device Description: The DIMISIL Scar Gel is manufactured from a medical grade silicone gel and is an amorphous paste that has minimal to no elasticity or strength.. The scar gel is supplied in 0.34 fl. oz. (10ml) tubes. The DIMISIL Scar Gel is intended to be used for topical management of keloid or hypertrophic scars secondary to trauma of the skin by surgery, burns, abrasions or lacerations.

Intended Use: The intended use for the DIMISIL Scar Gel is topical management of keloid or hypertrophic scars secondary to trauma of the skin by surgery, burns, abrasions or lacerations. Not for use on open wounds.

Predicate Device: The DIMISIL Scar Gel is substantially equivalent in material, design, function, and performance to the Kelocote marketed by Allied Biomedical Corporation of Ventura, CA and the Kelocote Scar Gel marketed by Hanson Medical, Inc. of Kingston, WA. All products have identical intended uses and are offered in similar quantites.

Packaging: The DIMISIL Scar Gel is offered non-sterile. The scar gel will be packaged in a aluminum tube with a puncture seal cap top and crimped end. Each tube will be labeled and identified with lot number for traceability. The labeled tube will be packaged in a screen printed chipboard box along with a package insert for inventory and shipment.

Sterilization: The DIMISIL Scar Gel is offered non-sterile and not intended to be sterilized.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 23 2003

Aesthetic and Reconstructive Technologies, Inc.
c/o Catherine Riple
5871 Lone Pine Place
Paso Robles, California 93446

Re: K023678
Trade/Device Name: DIMISIL Scar Gel
Regulation Name: Silicone Elastomer for Scar Management
Regulatory Class: Unclassified
Product Code: MDA
Dated: October 28, 2002
Received: November 1, 2003

Dear Ms. Riple:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1

510(k) Number (if known): K023678

Device Name: DIMISIL SCAR GEL

Indications For Use:

The intended use of the AART, Inc. "DIMISIL Scar Gel" is topical management of keloid or hypertrophic scars secondary to trauma of the skin by surgery, burns, abrasions or lacerations. Not for use on open wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE I NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(510(k) Number K023678

Prescription Use___ OR Over-The-Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-9